

In response, Applicant respectfully submits that these rejections are rendered moot by the amendments to claims 5 and 14-20 presented herein. Accordingly, withdrawal of these rejections is respectfully requested.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. 102 (b)

A. The Examiner rejected claims 1-12 and 14-20 under 102 (b) as anticipated by WO 98/24883.

In particular, the Examiner states:

"WO 98/24883 discloses similarly a solid composition comprising meiosis activating substance (MAS) and an additive, wherein the additive and organic solvent are components when added to MAS provide a composition which can be used to prepare an aqueous containing MAS. The preferred MAS is FF-MAS molecule which is 4,4-dimethyl-5 $\alpha$ -cholesta-8,14,24-triene-3 $\beta$ -ol. With respect to the percentages content of water, organic solvent; the prior art does not disclose the above percentages content as claimed. However, the ranges disclosed in the prior art overlaps the claimed ranges. Further, it is the Examiner's position that since the above characteristics (i.e., percentages content) are in the properties and not in the structure of the claimed formulation/composition claimed, and as such it is inherent characteristics/properties of the prior art composition/formulation (See e.g., page 1, lines 5-31; pages 7-12, and the claims).

In regard to claim 12 which is directed to a device comprising a hollow containing the claimed composition, the prior art discloses the teaching of growing culture medium in a hollow container, and as such, the delivery system has a container or a hollow device containing the composition of MAS and additive for the purpose of growing cells thereof. Thus, the reference clearly discloses a composition comprising MAS and additive of which can be dissolved in the aqueous medium in with a culturing system of a device containing a hollow composition thereof, and as such anticipates claims 1-12 and 14-20 as drafted." (pages 3-4 of the Office Action).

Applicant respectfully traverses this rejection.

WO 98/24883 relates to cell culture media containing a sterol stabilized by a surfactant, where the media may further contain a soluble carboxylic acid and/or an alcohol. (see, for example, the Abstract, page 5, lines 6-12 and page 7, lines 7-23 of the specification of WO 98/24883). In particular, the application discloses that it has been surprisingly found that "surfactant can be used to the exclusion of protein agents" to incorporate cholesterol and/or other sterols into serum-free media (page 5, lines 6-11, emphasis added) and that "the present invention provides a cell culture medium containing one or more synthetic lipids or lipid precursors, eg a sterol or a metabolically acceptable derivative thereof, in a solution stabilized by one or more surfactants and in the substantial absence of protein and of phospholipids" (page 5, lines 20-25, emphasis added). It is further disclosed that the "additive" to the cell culture medium may 1) comprise an alcohol, a sterol or a metabolically acceptable derivative and a soluble carboxylic acid or 2) equal volumes of 96% ethanol and water and 100g/l of the surfactant Pluronic F68 (page 11, lines 1-12, emphasis added).

By comparison, the present claims are directed to "a solid composition comprising a meiosis activating substance (MAS) and an additive which is a protein or a phosphoglyceride" or to an aqueous solution or a device comprising the aforementioned composition. As none of the compositions of WO 98/24883 contain a protein or a phosphoglyceride as an additive, WO 98/24883 cannot anticipate the claims and withdrawal of the rejection is respectfully requested.

B. The Examiner rejected claims 1-12 and 14-20 as being anticipated by WO 00/52142 for the reasons set forth above for the rejection over WO 98/24883.

In response, Applicant respectfully submits that the present application is entitled to claim the benefit of Danish application PA 1999 01308 filed September 16, 1999 and a certified copy of the aforementioned Danish application is submitted herewith. Upon receipt, Applicant will submit an executed substitute Declaration claiming the benefit of Danish application PA 1999 01308 filed September 16, 1999. As the present application was filed on September 14, 2000; ie, before November 29, 2000 and within one year of the filing

date of the aforementioned Danish application, the claim to benefit is believed to be timely submitted (see MPEP 201.13).

Accordingly, since the cited WO 00/52142 application was published on September 8, 2000; ie after the September 16, 1999 filing date of Danish application PA 1999 01308 to which benefit is claimed, the WO 00/52142 application is not prior art to the pending claims and withdrawal of this rejection is therefore respectfully submitted.

Applicant also notes for the record that the cited WO 00/52142 application was filed as a US application on August 14, 2001, is currently pending, and has been assigned serial no. 09/929,800.

C. The Examiner rejected claims 1-12 and 14-20 as being anticipated by US Patent No. 5,716,777 ("the '777 patent") for the reasons set forth above for the rejection over WO 98/24883.

Applicant respectfully traverses this rejection.

The '777 patent discloses pharmaceutical compositions useful in regulating meiosis in a mammalian germ cell where the compositions comprise at least one compound of formula I and a pharmaceutically acceptable carrier where examples of solid carriers are magnesium carbonate, magnesium stearate, dextrin, lactose, sugar, talc, gelatin, pectin, tragacanth, methyl cellulose, sodium carboxymethyl cellulose, low melting waxes and cocoa butter. (see claims and columns 3 and 4 of the '777 patent). As there is no disclosure in the '777 patent of a composition comprising a meiosis activating substance and an additive which is a protein or phospholipid, the present claims cannot be anticipated by the '777 patent. Accordingly, withdrawal of this rejection is respectfully requested.

In view of the above amendments and remarks, the present application is believed to be in condition for allowance.

Early and favorable consideration by the Examiner is respectfully solicited.

Respectfully submitted,

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PATENT TRADEMARK OFFICE

"Marked-Up" Copy of The Amended Claims

1. (Amended) A solid composition[,] comprising a meiosis activating substance (MAS) and an additive which is a protein or a phosphoglyceride. ←
5. (Amended) The composition of claim 1, wherein the MAS is selected from the group [comprising] consisting of 4,4-dimethyl-5 $\alpha$ -cholesta-8,14,24-triene-3 $\beta$ -ol; 4,4-dimethyl-5 $\alpha$ -cholest-8,14,24-trien-3 $\beta$ -ol hemisuccinate; 5 $\alpha$ -cholest-8,14-dien-3 $\beta$ -ol; 5 $\alpha$ -cholest-8,14-dien-3 $\beta$ -ol hemisuccinate; (20S)-cholest-5-en-3 $\beta$ ,20-diol; 3 $\beta$ -hydroxy-4,4-dimethyl-5 $\alpha$ -chola-8,14-dien-24-oic acid-N-(methionine) amide; and cholest-5-en-16 $\beta$ -ol.
14. (Amended) The composition of claim 2, wherein the water content is below 5% (weight/weight).
15. (Amended) The composition of claim 14, wherein the water content is below 1% (weight/weight).
16. (Amended) The composition of claim 3, wherein the organic solvent content is below 5% (weight/weight).
17. (Amended) The composition of claim 16, wherein the organic solvent content is below 1% (weight/weight).
18. (Amended) The composition of claim 4, wherein the MAS content is below 20% (weight/weight).

19. (Amended) The composition of claim 18, wherein the MAS content is below 10%  
(weight/weight).

20. (Amended) The composition of claim 19, wherein the MAS content is below 5%  
(weight/weight).